HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

September 26, 2000

CERTIFIED MAIL – RETURN RECEIPT REQUESTED

Harry T. Fan, President
Stason Pharmaceuticals, Inc.
11 Morgan
Irvine, CA 92618

W/L 85-00

Dear Mr. Fan:

During inspections of your manufacturing facility located at 11 Morgan, Irvine CA conducted July 10 through July 14 and July 28, 2000, our FDA investigators documented deviations from the Current Good Manufacturing Practices (CGMPs) for Finished Pharmaceuticals (Title 21, Code of Federal Regulations, (CFR) §210 and §211). Those deviations cause all drug products manufactured at your facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act). The violations from 21 CFR §210 and §211 include:

1. Failure to establish production and process control procedures designed to assure your drug products have the required identity, strength, quality and purity [21 CFR §211.100(a)]. For example, the validation protocol for [redacted] was approved on December 6, 1996; the 1st validation batch was manufactured on November 17, 1995. There were several significant deviations from the approved validation protocol noted by our investigators for this batch.

2. Failure of the quality control unit to approve procedures that affect the identity, strength, quality and purity of drug products [21 CFR §211.22(c)]. For example, [redacted] was manufactured at 95% of the batch size recorded in the Master Batch Record. These changes were made after release of the batch record for production by the quality control unit. There was neither an explanation provided in the batch record nor a deviation report filed for this change.

3. Failure to perform investigations into unexplained discrepancies of a batch or any of its components to meet specifications [211.192]. For example, you did not investigate Out of Specification (OOS) results obtained during blend uniformity testing of the final blend for [redacted]

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your Irvine, CA facility. We acknowledge the immediate corrective actions you took during the inspection and committed to in your response to the FDA-483 you submitted to the district office. However, it is your continuing responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. You should take prompt action to correct these deviations and prevent their recurrence. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts. Additionally, pending Antibiotic Form 6, New Drug Applications, Abbreviated New Drug Applications or export approval requests may not be approved until the above violations are corrected.

In addition, we offer the following comments:

During the inspection, it was established that your quality control unit has combined the functions of quality control and quality assurance. Along with the examples mentioned above, you were cited for several observations by our investigators that indicate your quality control unit is inadequate to perform its required functions. You should be aware that we consider this inadequacy to be highly significant.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed.

Your written response should be directed to the Food and Drug Administration, Attention:

Thomas L. Sawyer
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612

Sincerely,

Elizabeth A. Keville
Acting District Director

cc: California Department of Health Services, Food & Drug Branch
601 N. 7th Street
Sacramento, California 94234-7320
Attn: Stuart Richardson, Jr., Chief